510(K) SUMMARY

DBB-05 HEMODIALYSIS DELIVERY SYSTEM

SEP 2 8 2007

510(K) NUMBER: K061519

A. Submitter's Information

Name:	Nikkiso Co., LTD.
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Contact Person:	Masashi Yoshida, Manager Regulatory Affairs
Application Correspondent:	Fumiaki Kanai, PhD., President and CEO MIC International
Date Summary Prepared:	May 22, 2006

B. Device Information

Trade/Device Name:	DBB-05 Hemodialysis Delivery System
Regulation Number:	21 CFR §876.5860
Regulation Name:	High permeability hemodialysis system
Regulatory Class:	Class II
Product Code:	78 KDI
Classification Panel:	Gastroenterology/Urology

Description of Device

The DBB-05 Hemodialysis Delivery System is composed of a hydraulic unit for the delivery of dialysate and extracorporeal blood circuitry. The permeate is heated and deaerated in the hydraulic section, which is then mixed with concentrate and fed into the dialyser through the dialysate fluid feeder. The closed balancing system assures the amount of dialysate infused corresponds to the amount of dialysate extracted. The interior pressure of the dialyser is controlled automatically by adjustment of the Ultra Filtration (UF) amount and UF rate by the dialyser. Heparinization of the external circulating blood is performed with the heparin pump either by continuous or one-shot injection before it is passed on to the dialyser.

510(K) SUMMARY

DBB-05 HEMODIALYSIS DELIVERY SYSTEM

510(K) NUMBER: K061519

Description of Device (continued)

The DBB-05 Hemodialysis Delivery System uses both acetate dialysis and bicarbonate dialysis. Using the various functions of the device, the conductivity and UF profile can be programmed. In addition, DBB-05 Hemodialysis Delivery System incorporates all functions necessary for double-needle dialysis as well as single-needle dialysis treatment. The hydraulic unit is cleaned and disinfected using selectable cleaning programs and is equipped with the necessary protective systems for patient safety and correct operation.

C. Predicate Device Information

DBB-05 Hemodialysis Delivery System [K023509] (10/30/03)

D. Indications for Use/Intended Use

The DBB-05 Hemodialysis Delivery System is indicated for hemodialysis prescribed by physicians for adult and pediatric patients with acute or chronic renal failure. The DBB-05 is intended for hemodialysis performed in hospitals and dialysis clinics by a qualified operator.

E. Substantial Equivalence

1. Is the product a device?

YES – The DBB-05 Hemodialysis Delivery System is a device.

2. Does the new device have the same intended use?

YES – The intended use for the DBB-05 Hemodialysis Delivery System is equivalent to that for the Nikkiso DBB-05 Hemodialysis Delivery System and is as follows:

Intended Use: DBB-05 Hemodialysis Delivery System

The DBB-05 Hemodialysis Delivery System is indicated for hemodialysis prescribed by physicians for adult and pediatric patients with acute or chronic renal failure. The DBB-05 is intended for hemodialysis performed in hospitals and dialysis clinics by a qualified operator.

510(K) SUMMARY

DBB-05 HEMODIALYSIS DELIVERY SYSTEM

510(K) NUMBER: K061519

3. Does the device have technological characteristics that raise new types of safety or effectiveness questions?

NO – The DBB-05 Hemodialysis Delivery System is composed of a hydraulic. The technological characteristics of the DB-05 Hemodialysis Delivery System are equivalent to those of the original DB-05 Hemodialysis Delivery System [K023509] and raise no new types of safety or effectiveness questions.

4. Does descriptive or performance information demonstrate equivalence?

YES – Nikkiso Co., LTD. believes that the information provided in this submission clearly describes the DBB-05 Hemodialysis Delivery System and demonstrates that it is substantially equivalent to the original Nikkiso DBB-05 Hemodialysis Delivery System.

F. Safety Summary

Nikkiso CO., LTD. made several modifications to the original DBB-05 Hemodialysis Delivery System cleared under K023509. All design control activities including safety risk analysis and the verification and validation activities conducted as related to the risks proved that the modified DBB-05 Hemodialysis Delivery System is substantially equivalent in intended use, design, principle of operations, materials, specifications, performance, and contains the same fundamental scientific technology as the original DBB-05 Hemodialysis Delivery System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 28 2007

NIKKISO Co., Ltd.
c/o Fumiaki Kanai, Ph.D.
President and CEO
MIC International
4-2-1 Yushima, Bunkyou-ku
Tokyo 113-0034
JAPAN

Re: K061519
Trade/Device Name: DBB-05 Hemodialysis Delivery System
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: August 24, 2007
Received: August 29, 2007

Dear Dr. Kanai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K061519

Device Name: DBB-05 Hemodialysis Delivery System

Indications for Use: The DBB-05 Hemodialysis Delivery System is indicated for hemodialysis prescribed by physicians for adult and pediatric patients with acute or chronic renal failure. The DBB-05 is intended for hemodialysis performed in hospitals and dialysis clinics by a qualified operator.

Prescription Use ✓ **OR** **Over-the Counter Use** _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON OTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carolyn Y Neuland for N. Bogdan

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K061519